



FFP2 Respirator

https://drive.google.com/file/d/1oBk3_Nxh_xjvRJK-1qWarUhgcIK2Zd-S/view?usp=sharing

PRODUCT DOCUMENTS BELOW

TECHNICAL DATA SHEET

Particle Filtering Half Mask

FFP2 NR

Non-Sterile

Description

MY3D2: FFP2 NR, Non-sterile, Large size, White, With nose clip

Dimensions (Unfolded drawing)

	Length	Width
MY3D2	232 mm	126 mm

Properties

Basis weight of non-woven fabrics (outer layers): 48 g/m²

Basis weight of non-woven fabrics (inner layers): 25 g/m²

Basis weight of Nano fabrics (middle layers): 40 g/m²

Basis weight of Hot air cotton (middle layers): 45 g/m²

Particle Filtering Half Mask as defined by EN 149:2001+A1:2009.

Test results as per EN 149:2001+A1:2009 available upon request.



Indication

The mask can filter the particles in the air, and block the droplets, blood, body fluids and secretions. It is safe and reliable. Single use product.

Counter indication

None in particular.

Main materials

Mask body: Made of non-woven fabrics (inner and outer layers),

Hot air cotton(middle layers) and Nano fabrics (middle layers).

Nose clip: Polyethylene + Zinc wire

Ear loop: Spandex + Nylon

Sterilization

Products are not sterilized.

Packaging

MY3D2: 10/PK, 1000/carton

Manufacturing

Products are manufactured in China.

The quality system of the manufacturing sites is ISO 13485 Compliant.

Regulatory information

Name of regulatory authority: SGS FIMKO OY, Notified Body 0598.

Product marketing licence number, Module B: Certificate FI20/965826,

Module C2: Certificate CN20/42066.

Storage

Store the product in a clean room with a relative humidity of less than 80% at room temperature, no corrosive gases, cool, dry, and well ventilated.

Shelf life

3 years after month of production.

Test Report

SL52025244872201TX

Date: April 29, 2020

Page 1 of 9

GUANGZHOU BIOFIL AIR PURIFICATION MATERIALS CO., LTD
ROOM 201, 2ND FLOOR, WORKSHOP B, NO.1 DOUTANG ROAD, YONGHE DEVELOPMENT ZONE,
GUANGZHOU, CHINA 511356

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Particle filtering half mask

Style No. : MY3D2

Composition : (A) non-woven fabrics

Sample Color : (A) White

Manufacturer : GUANGZHOU BIOFIL AIR PURIFICATION MATERIALS CO., LTD

Country of Destination : European countries

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Apr 15, 2020

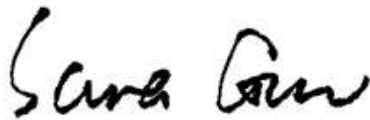
Testing Period : Apr 15, 2020 - Apr 29, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Conclusion:

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center



Sara Guo (Account Executive)



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Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements, Testing, Marking

(EN 149:2001+A1:2009)

Clause 7.4 Packaging#

(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Comply	Pass

Clause 7.5 Material#

(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Comply	Pass
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Comply	
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting#

(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance#

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass



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Clause 7.8 Finish of Parts#

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage#

(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
<p>The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3</p> <p>and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3</p>	Detail refer to Appendix 1	Pass

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	8.13	8.23	8.28	8.18	8.31	8.2
Gong	2	A.R.	7.33	7.84	7.64	7.39	7.71	7.6
Yu	3	A.R.	5.90	6.47	6.32	5.90	6.32	6.2
Hu	4	A.R.	6.32	6.60	6.71	6.61	6.45	6.5
Xu	5	A.R.	7.89	8.07	8.00	8.04	8.10	8.0
Deng	6	T.C.	6.32	6.41	6.79	6.48	6.53	6.5
Liu	7	T.C.	5.62	5.88	5.87	5.93	5.80	5.8
Zhi	8	T.C.	6.11	6.60	6.53	6.49	6.22	6.4
Fang	9	T.C.	5.11	5.39	5.13	5.24	5.53	5.3
Chen	10	T.C.	7.77	7.77	7.88	8.09	8.17	7.9
All 50 individual exercise results were not greater than 11 %						Pass		
9 out of 10 individual wearer arithmetic means were not greater than ≤ 8 %								

Facial Dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63



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Fang	115	129	120	50
Chen	116	150	132	56
Lv	110	121	110	53

Clause 7.9.2 Penetration of Filter Material#

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

Test Requirement			Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.			Detail refer to Appendix 2	Pass
Classifica tion	Maximum penetration of test aerosol			
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min		
	% max.	% max.		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

Appendix 2: Summarization of Test Data
Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.682	Pass
		12	0.591	
		13	0.674	
	Simulated wearing treatment	14	0.726	
		15	0.731	
		16	0.745	
	Mechanical strength + Temperature conditioned	17	0.821	
		18	0.865	
		19	0.799	
Paraffin oil test	As received	20	1.24	
		21	1.31	
		22	1.35	
	Simulated wearing treatment	23	1.26	
		24	1.22	
		25	1.38	
	Mechanical strength + Temperature conditioned	26	1.49	
		27	1.47	
		28	1.45	
Flow conditioning: Single filter: 95.0 L/min				



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Clause 7.10 Compatibility with Skin#

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability#

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result	Assessment
As received	29	Burn for 2 s	Pass
	30	Burn for 1 s	
Temperature conditioned	31	Burn for 1 s	
	32	Burn for 1 s	

Clause 7.12 Carbon Dioxide Content of The Inhalation Air#

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result	Assessment
As received	33	0.42%	Mean value 0.4% Pass
	34	0.42%	
	35	0.41%	

Clause 7.13 Head Harness#

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	Comply	



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Clause 7.14 Field of Vision#

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)#

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to No exhalation valve	N.A.
(b) If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	Not applicable due to No exhalation valve	
(c) Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	

Clause 7.16 Breathing Resistance#

(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement				Results	Comment																						
<p>The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.</p> <table><tr><th rowspan="3">Classification</th><th colspan="3">Maximum permitted resistance (mbar)</th></tr><tr><th colspan="2">Inhalation</th><th>Exhalation</th></tr><tr><th>30 l/min</th><th>95 l/min</th><th>160 l/min</th></tr><tr><td>FFP1</td><td>0.6</td><td>2.1</td><td>3.0</td></tr><tr><td>FFP2</td><td>0.7</td><td>2.4</td><td>3.0</td></tr><tr><td>FFP3</td><td>1.0</td><td>3.0</td><td>3.0</td></tr></table>				Classification	Maximum permitted resistance (mbar)			Inhalation		Exhalation	30 l/min	95 l/min	160 l/min	FFP1	0.6	2.1	3.0	FFP2	0.7	2.4	3.0	FFP3	1.0	3.0	3.0	Detail refer to Appendix 5	Pass
					Classification	Maximum permitted resistance (mbar)																					
						Inhalation		Exhalation																			
				30 l/min		95 l/min	160 l/min																				
				FFP1	0.6	2.1	3.0																				
				FFP2	0.7	2.4	3.0																				
				FFP3	1.0	3.0	3.0																				



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Appendix 5: Summarization of Test Data

Breathing resistance (mbar)

	Flow rate		36					37					38				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30 l/min	0.6	0.7	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.6	0.7	0.7	0.7
		95 l/min	2.1	2.3	2.2	2.2	2.1	2.2	2.3	2.1	2.1	2.1	2.2	2.3	2.2	2.3	2.2
	Exhalation	160 l/min	2.6	2.8	2.7	2.8	2.7	2.7	2.7	2.8	2.7	2.7	2.8	2.7	2.6	2.6	2.6
	Flow rate		39					40					41				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Simulated wearing treatment	Inhalation	30 l/min	0.7	0.7	0.7	0.6	0.6	0.7	0.7	0.6	0.7	0.6	0.7	0.6	0.7	0.7	0.6
		95 l/min	2.3	2.2	2.2	2.1	2.2	2.1	2.2	2.2	2.1	2.3	2.1	2.2	2.1	2.2	2.2
	Exhalation	160 l/min	2.8	2.7	2.6	2.8	2.8	2.7	2.7	2.7	2.7	2.7	2.7	2.8	2.7	2.6	2.7
	Flow rate		42					43					44				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	Inhalation	30 l/min	0.7	0.7	0.7	0.7	0.7	0.6	0.7	0.6	0.7	0.7	0.7	0.6	0.7	0.7	0.7
		95 l/min	2.1	2.2	2.3	2.2	2.3	2.1	2.2	2.1	2.1	2.3	2.3	2.3	2.2	2.2	2.1
	Exhalation	160 l/min	2.7	2.8	2.7	2.8	2.8	2.6	2.8	2.8	2.7	2.8	2.7	2.6	2.8	2.7	2.8
Assessment	Pass																

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

Clause 7.17 Clogging#

(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment
<p><u>Clause 7.17.2 Breathing resistance</u></p> <p><u>Valved particle filtering half masks:</u></p> <p>After clogging the inhalation resistances shall not exceed:</p> <p>FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow</p> <p>The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow.</p> <p><u>Valveless particle filtering half masks:</u></p> <p>After clogging the inhalation and exhalation resistances shall not exceed:</p> <p>FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow</p>	Optional for single shift device only	N.A.



Test Requirement			Results	Comment																		
<p><u>Clause 7.17.3 Penetration of filter material</u> All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.</p> <table><tr><th rowspan="4">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr><tr><th>Sodium chloride test 95 l/min</th><th>Paraffin oil test 95 l/min</th></tr><tr><th>%</th><th>%</th></tr><tr><th>max.</th><th>max.</th></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table>			Classification	Maximum penetration of test aerosol		Sodium chloride test 95 l/min	Paraffin oil test 95 l/min	%	%	max.	max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	Optional for single shift device only	N.A.
Classification	Maximum penetration of test aerosol																					
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min																				
	%	%																				
	max.	max.																				
FFP1	20	20																				
FFP2	6	6																				
FFP3	1	1																				

Clause 7.18 Demountable Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No demountable parts	N.A.

This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1499.



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Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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